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EXAMINER

TRAN, MY CHAU T

ART UNIT

PAPER NUMBER

1639

DATE MAILED: 07/10/2003

21

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/848,727

Applicant(s)

GAU, VINCENT JEN-JR.

Examiner

My-Chau T. Tran

Art Unit

1639

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 May 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 and 51-74 is/are pending in the application.
- 4a) Of the above claim(s) 53-74 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20, 51 and 52 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☒ The proposed drawing correction filed on 05 May 2003 is: a) ☒ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment filed 5/5/03 in Paper No. 20 is acknowledged and entered.

Claims 21-50 are canceled by the amendment. Claims 1, and 3-20 are amended by the amendment. Claims 51-74 are added by the amendment.

2. Claims 1-20 and 51-74 are pending.

Election/Restrictions

3. Newly submitted claims 51-74 directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

The pending claims (Claims 1-20, and 51-74) are group as follows:

- a. Group I is Claims 1-20 (original invention) and 51-52 (newly submitted claims).
- b. Group II is Claims 53-64 (newly submitted claims).
- c. Group III is Claim 65-74 (newly submitted claims).

4. Inventions of Group I (process of use) and Group II (product) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process such as the method of drug screening or the method of DNA hybridization.

5. Inventions of Group I and Group III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions the different inventions as claimed have different method steps that have different functions and effects.

The method step of deterring from the signal output the presence and quantity of the target analyte in the sample reagent of Group I is not required by the claims of Group III. The method step of forming at least two electrically conductive electrodes on the substrate of Group III is not required by the claims of Group I.

6. Inventions of Group II (product) and Group III (process of making) are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed can be made by another and materially different process such as chemical vapor deposition or electropolymerization.

7. Because these inventions are distinct for the reasons given above and the searches required are not co-extensive thus requiring a burdensome search, restriction for examination purposes as indicated is proper. Additionally, different patentability considerations are involved for each group. For example, a patentability determination for Group III would involve a

Art Unit: 1639

determination of the patentability of the method of forming a microfabricated biosensor while a patentability determination for Group I would involve a consideration of the patentability of the method of detecting the presence of the target analyte in a sample reagent. These considerations are very different in nature.

8. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 53-74 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Drawings

9. The corrected or substitute drawings were received on 5/5/03 for Figure 29. These drawings are acceptable. However, applicant did not correct any of the informalities indicated on the attached "Notice of Draftsperson's Patent Drawing Review," PTO-948 mailed on 1/28/03 with the previous Office Action. In order to avoid abandonment of this application, correction is required in reply to the Office action. The correction will not be held in abeyance.

Specification

10. The rewritten abstract of the disclosure is acknowledged and entered.

11. Claims 1-20 and 51-52 are treated on the merit in this Office Action.

Art Unit: 1639

12. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Maintained Rejections

Claim Rejections - 35 USC § 102

13. Claims 1-9, 11-13, and 51-52 (newly added claims) are rejected under 35 U.S.C. 102(b) as being anticipated by Cozzette et al. (US Patent 5,200,051). (*Note: the newly added claims ⁵¹27-⁵²30 would now also be included in this rejection.*)

Cozzette et al. disclose a method of electrochemical assay using a biosensor, which is an electrode, to detect changes in concentration of electroactive species (col. 46, lines 13-18). The method comprise of preparing a solution of an analyte/label of interest and contacting it with the biosensor (col. 46, lines 19-65). The receptor immobilized on the biosensor reacts with the analyte forming a complex and the biosensor is in contact with the substrate, which reacts with label of the complex. This reaction initiates a sequence of steps, which effectuate changes in the concentration of the electroactive species, which are chemically measured (col. 46, lines 33-43) (referring to claim 4). The measurement provides for the determination of the corresponding analyte concentration in the sample (referring to claim 1). The solution comprise of biological fluid (col. 18, lines 23-34) (referring to claim 3). The substrate comprise of silicon, glass, or plastic (col. 25, lines 36-44) (referring to claims 5 and 6). The electrode comprise of gold or platinum (col. 25, lines 2-8) (referring to claims 7-8 and 13). A metal-substrate adhesive comprise of titanium (col. 25, lines 55-61) (referring to claims 2 and 9). The biosensor comprise of three conductive electrodes (see fig. 2) (referring to claim 12). Figure 4 shows an electrode

Art Unit: 1639

well structure (referring to claim 11). Therefore, the method of Cozzette et al. anticipates the presently claimed invention.

Additionally, Cozzette et al. disclose that the titanium layer serves as an adhesive layer between the iridium layer, which is the indicator electrode, and the substrate (refers to claim 51) and also as a conducting signal lines to the contact pads (refers to claim 52) (col. 24, lines 50-51; col. 25, lines 58-61).

Response to Arguments

14. Applicant's argument(s) directed to the above rejection under 35 USC 102(b) as being anticipated by Cozzette et al. (US Patent 5,200,051) for claims 1-9 and 11-13 was considered but they are not persuasive for the following reasons.

Applicant contends that “[C]ozzette does not teach a biosensor having a plurality of electrodes that each consist “of a single layer of an electrically conductive material”. Therefore, Cozzette et al. do not anticipates the presently claimed invention.

Applicant's arguments are not convincing since Cozzette et al. do teach a biosensor having a plurality of electrodes and that each electrode consist “of a single layer of an electrically conductive material”. Cozzette et al. disclose an “[a]mperometric base sensor that is a particular embodiment of the instant invention is fabricated on a substantially planar silicon substrate by means of photolithography in combination with the plasma deposition of metallic substances. The base sensor may comprise a unit cell containing two catalytic electrodes (i.e. an indicator electrode and a reference electrode) of identical geometry and area. This configuration allows a differential type of measurement because on only one of these catalytic electrodes is established a biolayer with active enzyme. Such a differential measurement may, in turn, enable the device

Art Unit: 1639

to measure a current due to the activity of selected bioactive molecules over and above a background level, especially in circumstances where an interfering species may not be readily excluded by a permselective membrane' (col. 24, lines 7-21). This biosensor of Cozzette et al. as shown in figure 2 comprises of an indicator electrode and two reference electrodes (*'a plurality of electrodes'*) (col. 24, lines 43-55). The substrate comprise of silicon and silicon dioxide (substrate surface). The indicator electrode is the iridium electrocatalyst layer (metal layer) (*'a single layer of an electrically conductive material'*). The reference electrode is a silver electrode that comprises of a "combination" of silver and silver chloride (*'a single layer of an electrically conductive material'*) shown as reference number 4 and 4' in figure 2 since *'silver electrode which is subsequently chloridized is most preferred as the reference electrode'* (col. 25, lines 6-8). Beneath each electrode is a titanium layer that serves as an adhesive between the metal layer and the substrate surface (col. 25, lines 58-61) (this layer refers to claim 2). Therefore, the biosensor and the electrode structure of Cozzette et al. anticipate the biosensor and electrode structure of the presently claimed invention.

Claim Rejections - 35 USC § 103

15. Claims 1-2 and 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cozzette et al. (US Patent 5,200,051) in view of Heller et al. (US Patent 5,403,700).

Cozzette et al. disclose a method of electrochemical assay using a biosensor, which is an electrode, to detect changes in concentration of electroactive species (col. 46, lines 13-18). The method comprise of preparing a solution of an analyte/label of interest and contacting it with the biosensor (col. 46, lines 19-65). The receptor immobilized on the biosensor reacts with the

Art Unit: 1639

analyte forming a complex and the biosensor is in contact with the substrate, which reacts with label of the complex. This reaction initiates a sequence of steps, which effectuate changes in the concentration of the electroactive species, which are chemically measured (col. 46, lines 33-43) (referring to claim 4). The measurement provides for the determination of the corresponding analyte concentration in the sample (referring to claim 1). The solution comprise of biological fluid (col. 18, lines 23-34) (referring to claim 3). The substrate comprise of silicon, glass, or plastic (col. 25, lines 36-44) (referring to claims 5 and 6). The electrode comprise of gold or platinum (col. 25, lines 2-8) (referring to claims 7-8 and 13). A metal-substrate adhesive comprise of titanium (col. 25, lines 55-61) (referring to claims 2 and 9). The biosensor comprise of three conductive electrodes (see fig. 2) (referring to claim 12). Figure 4 shows an electrode well structure (referring to claim 11).

The method of Cozzette et al. does not expressly disclose that the adhesive metal layer is chromium.

Heller et al. disclose a biocompatible thin film electrical component (col. 1, lines 10-17). The film comprise of a silicon substrate (col. 1, lines 40-42), an adhesive layer that bond a metal layer to the substrate (col. 6, lines 54-68 to col. 7, lines 1-4). The adhesive layer is metal comprises of chromium or titanium.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to include a chromium metal adhesive as taught by Heller et al. in the method of Cozzette et al. One of ordinary skill in the art would have been motivated to include a chromium metal adhesive in the method of Cozzette et al. because Heller et al. have indicated that chromium and titanium are suitable metal adhesive and Cozzette et al. uses a titanium metal

Art Unit: 1639

adhesive since applicant has not disclosed that a chromium metal adhesive solves any stated problem or is for any particular purpose, it appears that the invention would perform equally well with either chromium or titanium as metal adhesive.

Response to Arguments

16. Applicant's argument(s) directed to the above rejection under 35 USC 103(a) as being unpatentable over Cozzette et al. (US Patent 5,200,051) in view of Heller et al. (US Patent 5,403,700) for claims 1-2 and 10 was considered but they are not persuasive for the following reasons.

Applicant argues that “[C]ozzette does not teach a biosensor having a plurality of electrodes that each consist “of a single layer of an electrically conductive material””. Therefore, Cozzette et al. in view of Heller et al. is not obvious over the presently claimed invention.

Applicant's arguments are not convincing since Cozzette et al. do teach a biosensor having a plurality of electrodes and that each electrode consist “of a single layer of an electrically conductive material” as discussed in the rejection under 35 USC 102(b) above. Therefore, Cozzette et al. in view of Heller et al. is obvious over the presently claimed invention.

17. Claims 1-2 and 14-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cozzette et al. (US Patent 5,200,051) in view of Han et al. (US Patent 6,268,161 B1).

Cozzette et al. disclose a method of electrochemical assay using a biosensor, which is an electrode, to detect changes in concentration of electroactive species (col. 46, lines 13-18). The method comprise of preparing a solution of an analyte/label of interest and contacting it with the biosensor (col. 46, lines 19-65). The receptor immobilized on the biosensor (referring to claim

Art Unit: 1639

20) reacts with the analyte forming a complex and the biosensor is in contact with the substrate, which reacts with label of the complex. This reaction initiates a sequence of steps, which effectuate changes in the concentration of the electroactive species, which are chemically measured (col. 46, lines 33-43). The measurement provides for the determination of the corresponding analyte concentration in the sample (referring to claim 1). The solution comprise of biological fluid (col. 18, lines 23-34). The substrate comprise of silicon, glass, or plastic (col. 25, lines 36-44) (referring to claim 15). The electrode comprise of gold or platinum (col. 25, lines 2-8) (referring to claims 16-17). A metal-substrate adhesive comprise of titanium (col. 25, lines 55-61) (referring to claims 2 and 18). The method further comprise of a calibration step (col. 64, lines 5-21). Figure 4 shows an electrode well structure (referring to claim 19).

The method of Cozzette et al. does not expressly disclose that calibration step comprising calibration solution and obtaining a signal.

Han et al. disclosed a biosensor for measuring the concentration of organic molecules in a solution (col. 1, lines 16-17). Han et al. claim a method of using the biosensor that included a calibration step (Han: col. 16, claim 20). The claim method step includes a control solution (calibration solution) and obtaining a signal.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to include a calibration step comprising calibration solution and obtaining a signal as taught by Han et al. in the method of Cozzette et al. One of ordinary skill in the art would have been motivated to include a calibration step comprising calibration solution and obtaining a signal in the method of Cozzette et al. for the advantage of determining the performance of the electrode before the analysis of the sample since both Cozzette et al. and Han

Art Unit: 1639

et al. disclose a method of measuring the concentration of the organic molecules in a solution (Cozzette: col. 46, lines 13-18; Han: col. 1, lines 16-17).

Response to Arguments

18. Applicant's argument(s) directed to the above rejection under 35 USC 103(a) as being unpatentable over Cozzette et al. (US Patent 5,200,051) in view of Han et al. (US Patent 6,268,161 B1) for claims 1-2 and 14-20 was considered but they are not persuasive for the following reasons.

Applicant contends/argues/alleges that “[C]ozzette does not teach a biosensor having a plurality of electrodes that each consist “of a single layer of an electrically conductive material””. Therefore, Cozzette et al. in view of Han et al. is not obvious over the presently claimed invention.

Applicant's arguments are not convincing since Cozzette et al. do teach a biosensor having a plurality of electrodes and that each electrode consist “of a single layer of an electrically conductive material” as discussed in the rejection under 35 USC 102(b) above. Therefore, Cozzette et al. in view of Han et al. is obvious over the presently claimed invention.

Conclusion

19. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

Art Unit: 1639


MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to My-Chau T. Tran whose telephone number is 703-305-6999. The examiner is on *Increased Flex Schedule* and can normally be reached on Monday: 8:00-2:30; Tuesday-Thursday: 7:30-5:00; Friday: 8:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J. Wang can be reached on 703-306-3217. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1123.

mct
July 10, 2003



ANDREW WANG
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